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Mercer et al.

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(54) **FEEDBACK SYSTEM AND METHOD FOR ASSESSING FIXATION AND STABILITY OF IMPLANTABLE LEADS**

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G01N 3/08 (2006.01)
(Continued)

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CPC ***G01N 3/08*** (2013.01); ***A61N 1/057*** (2013.01); ***G01M 99/007*** (2013.01);
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CPC . G01N 19/04; G01N 2203/0017; G01N 3/04; G01N 3/08; A61N 1/057; A61N 1/05; A61N 2001/0578; A61B 2019/464; A61B 17/3468
USPC .... 73/856, 859, 860, 826, 830, 831, 833, 73/834, 150 A, 150 R, 862; 606/1, 129, 606/108; 607/127, 116, 128
See application file for complete search history.

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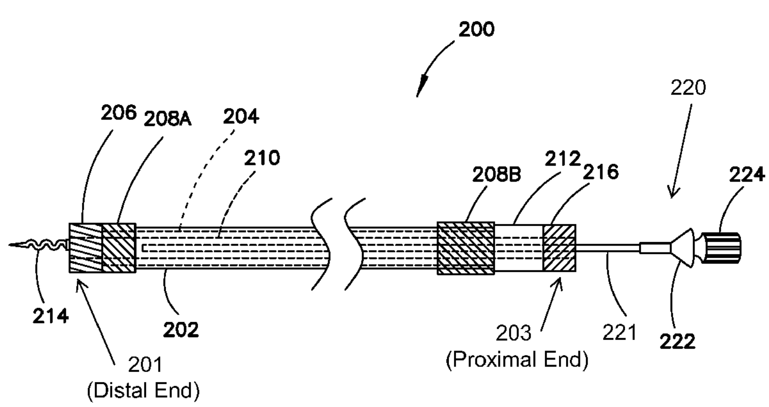
(57) **ABSTRACT**

A lead fixation and stability feedback assembly for testing stability and anchoring of a fixation tip of a distal end of an implantable lead to a tissue is disclosed. The assembly includes a first member including a first coupling arrangement configured to couple to a proximal end of an implantable lead, wherein the proximal end of the implantable lead is coupled to a distal end of the implantable lead configured to be anchored to a tissue, and a second member including a second coupling arrangement configured to couple the first member to the second member, the second coupling arrangement configured to decouple the second member from the first member when a predetermined force is applied to pull the second member away from the first member to thereby test the anchoring of the distal end of the implantable lead to the tissue.

18 Claims, 13 Drawing Sheets



(51) **Int. Cl.**

G01M 99/00	(2011.01)
G01N 19/04	(2006.01)
A61B 19/00	(2006.01)
A61N 1/05	(2006.01)
G01N 3/04	(2006.01)
A61B 17/34	(2006.01)

(52) **U.S. Cl.**

CPC *A61B 17/3468* (2013.01); *A61B 2019/464* (2013.01); *A61N 1/05* (2013.01); *A61N 2001/0578* (2013.01); *G01N 3/04* (2013.01); *G01N 19/04* (2013.01); *G01N 2203/0017* (2013.01)

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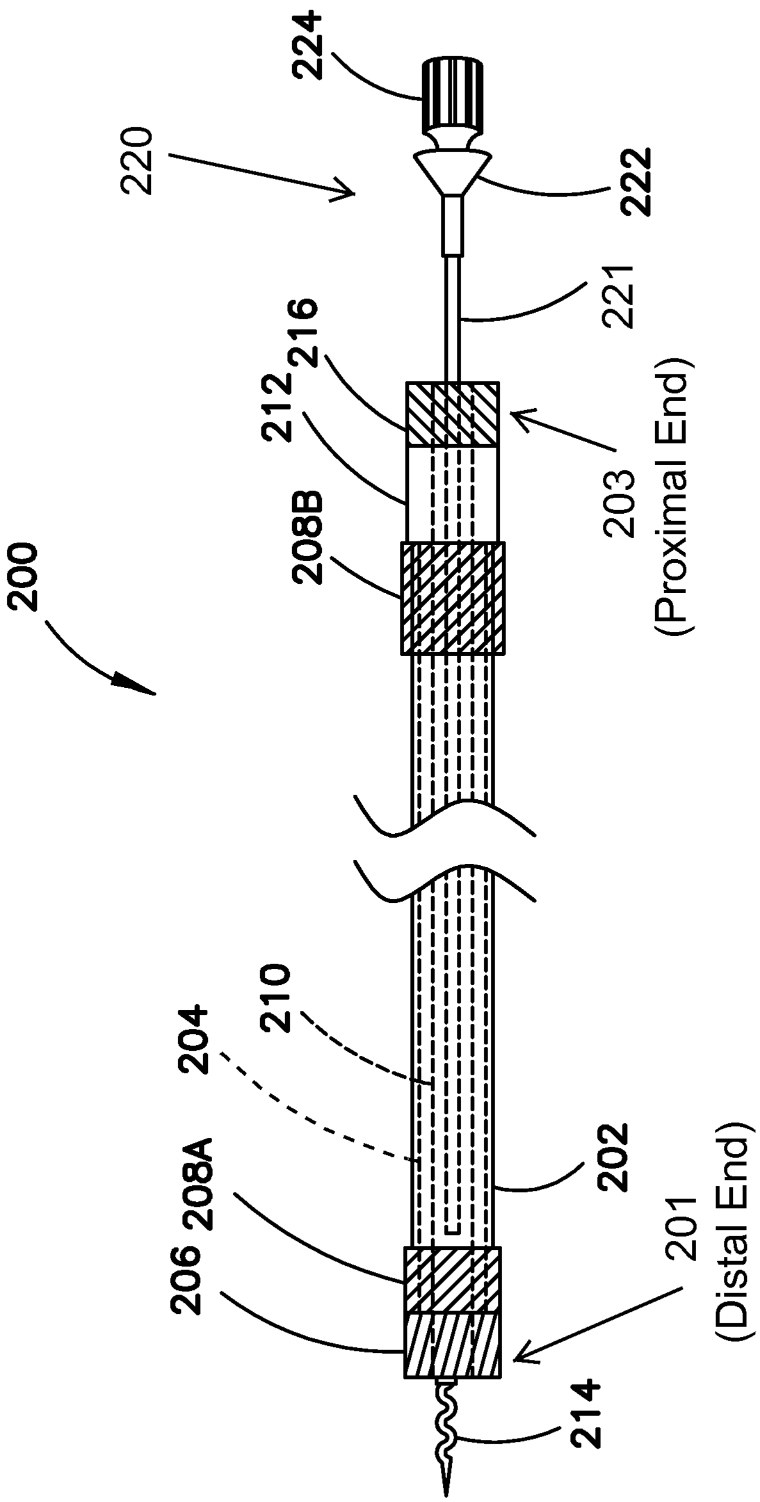

200
224
220
222
221
216
212
208B
203
(Proximal End)
210
204
202
208A
206
201
(Distal End)
214

FIG. 1A

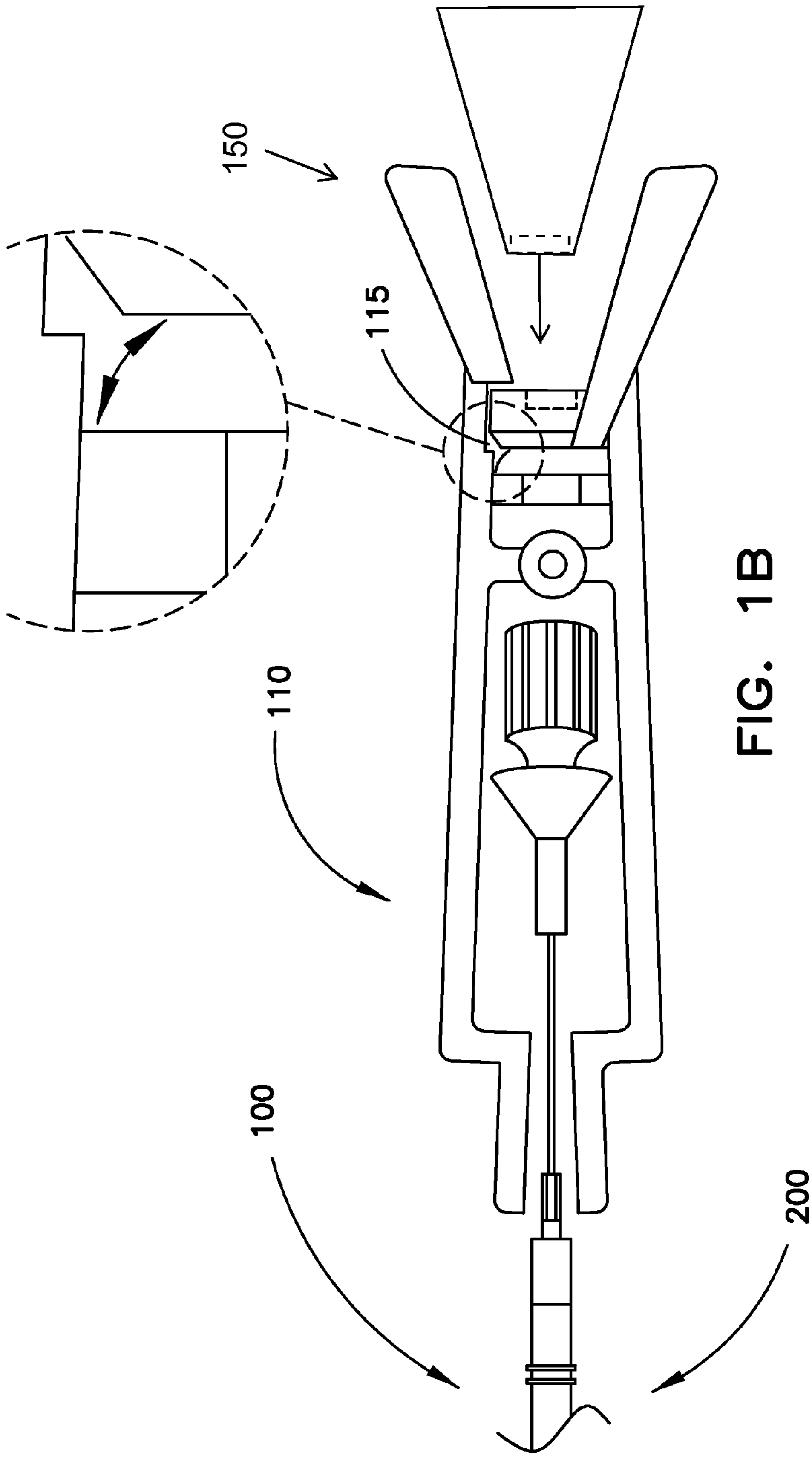

FIG. 1B

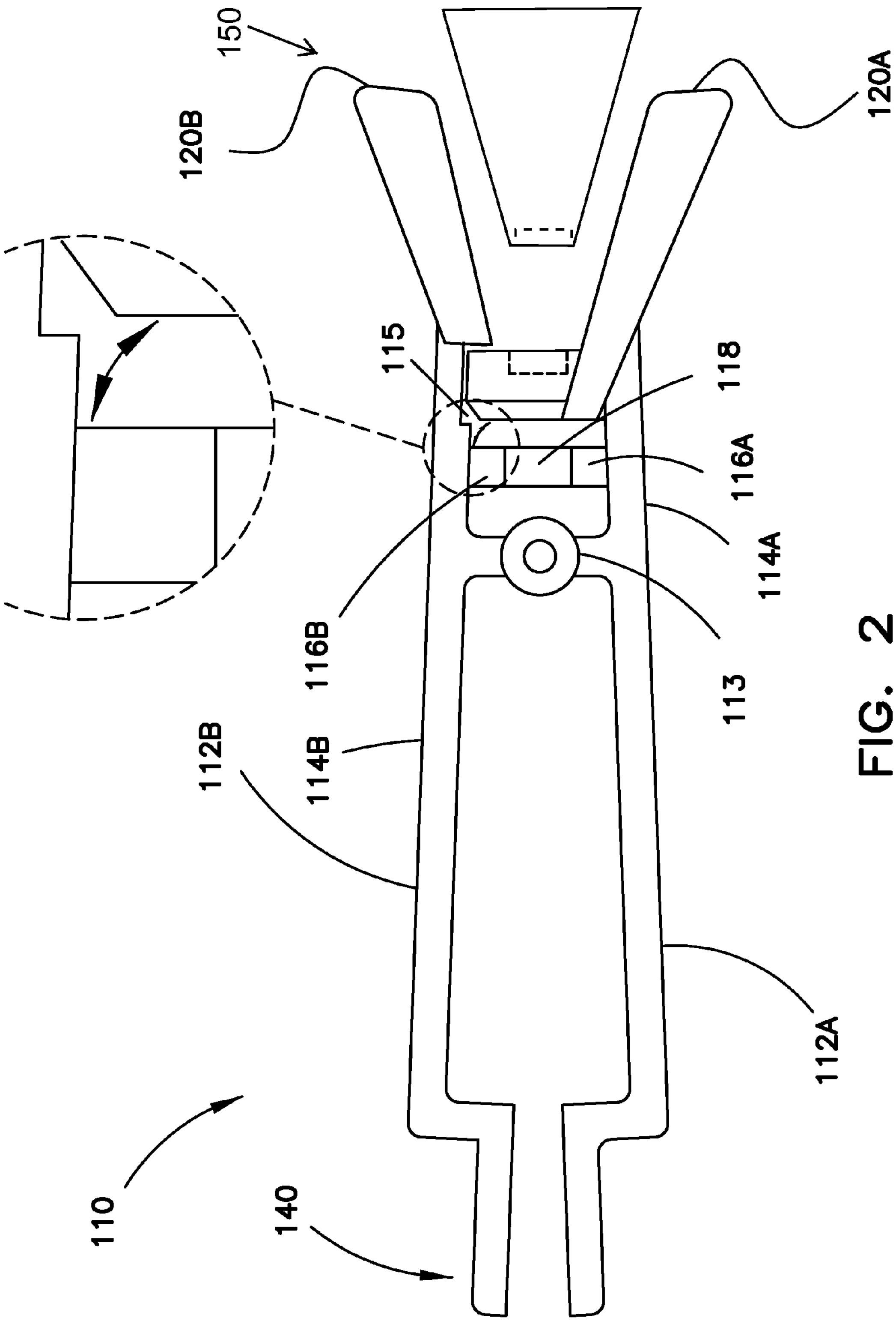
150
120B
120A
115
118
116A
114A
113
116B
112B
114B
112A
110
140

FIG. 2

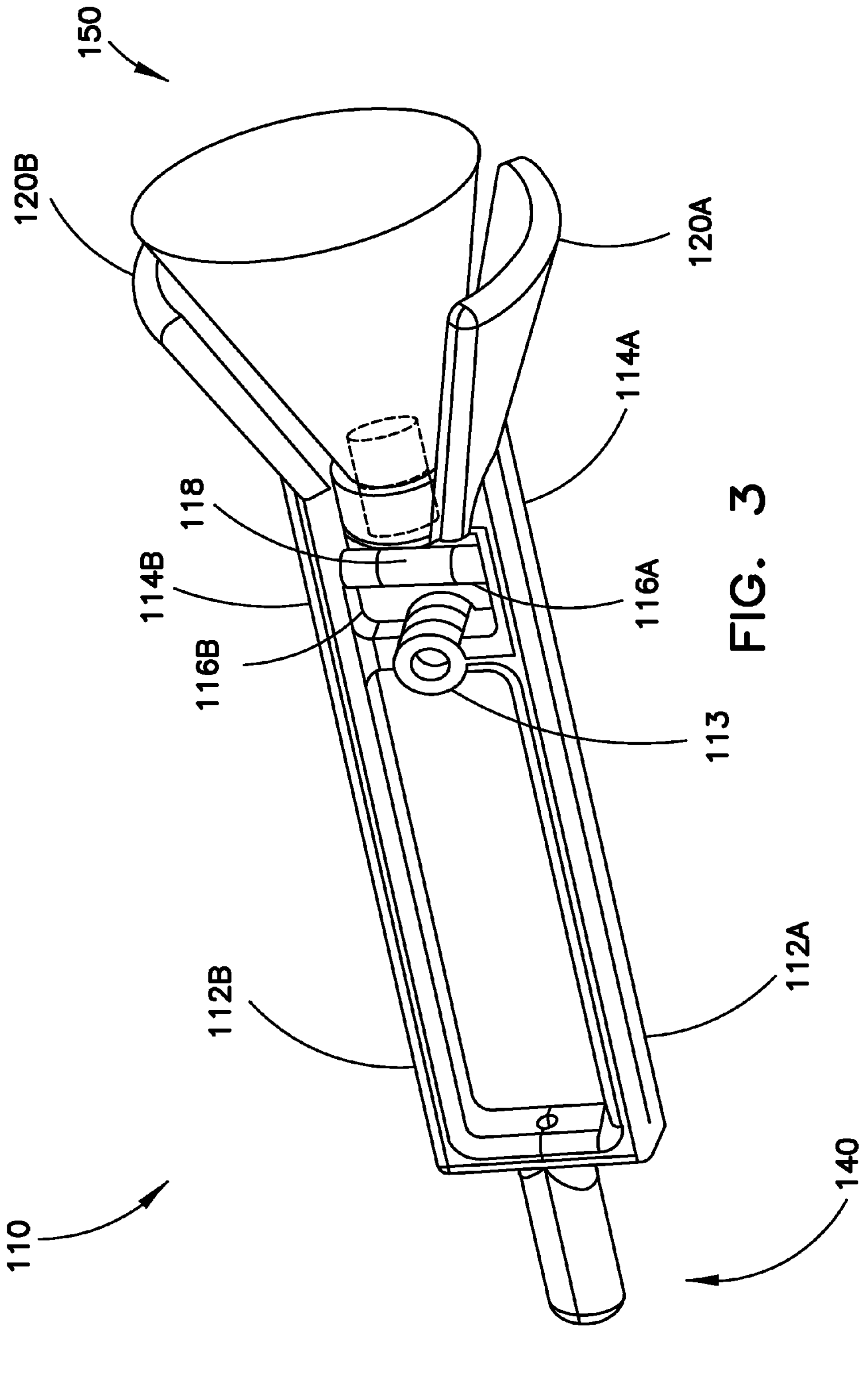

FIG. 3

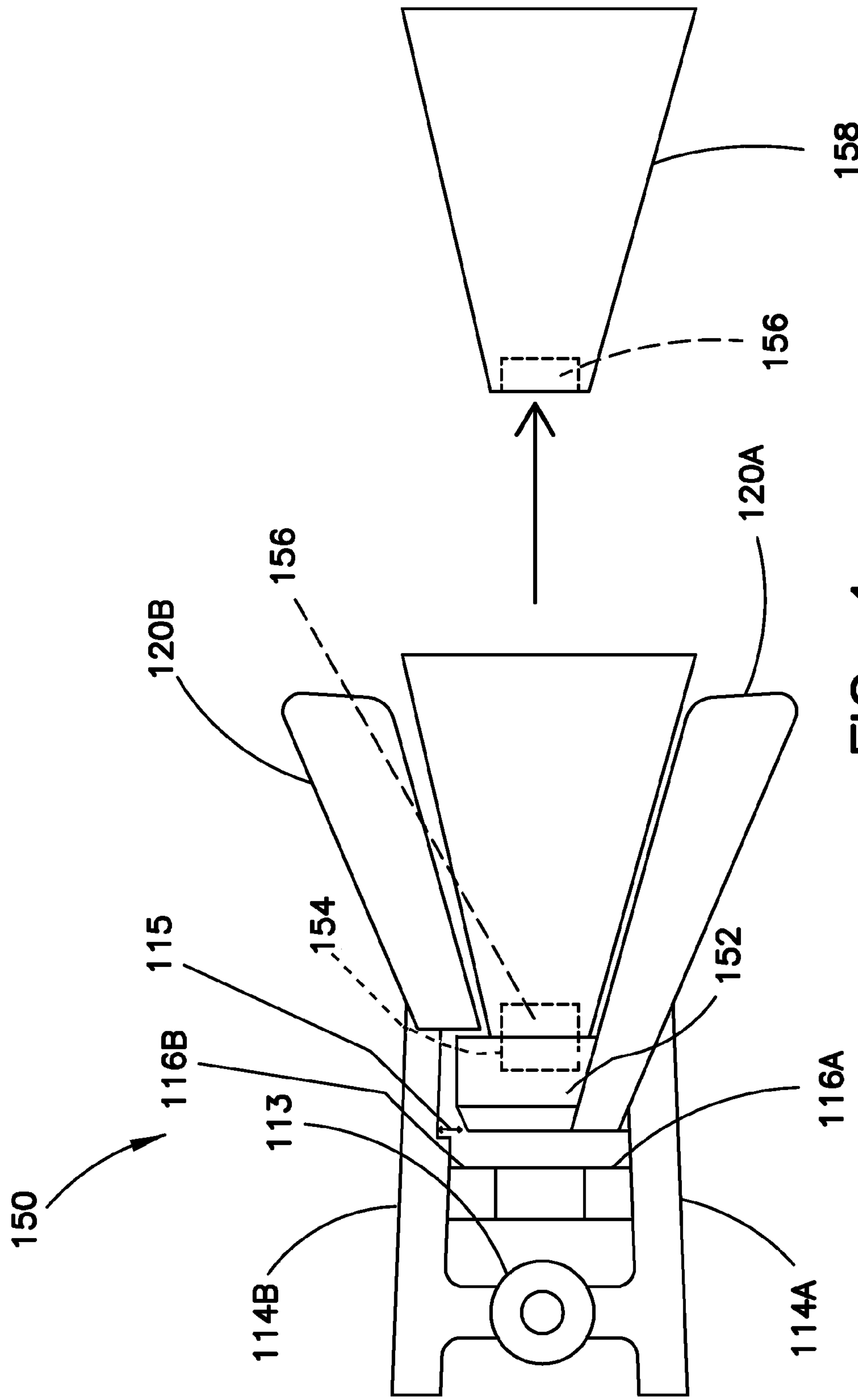

FIG. 4

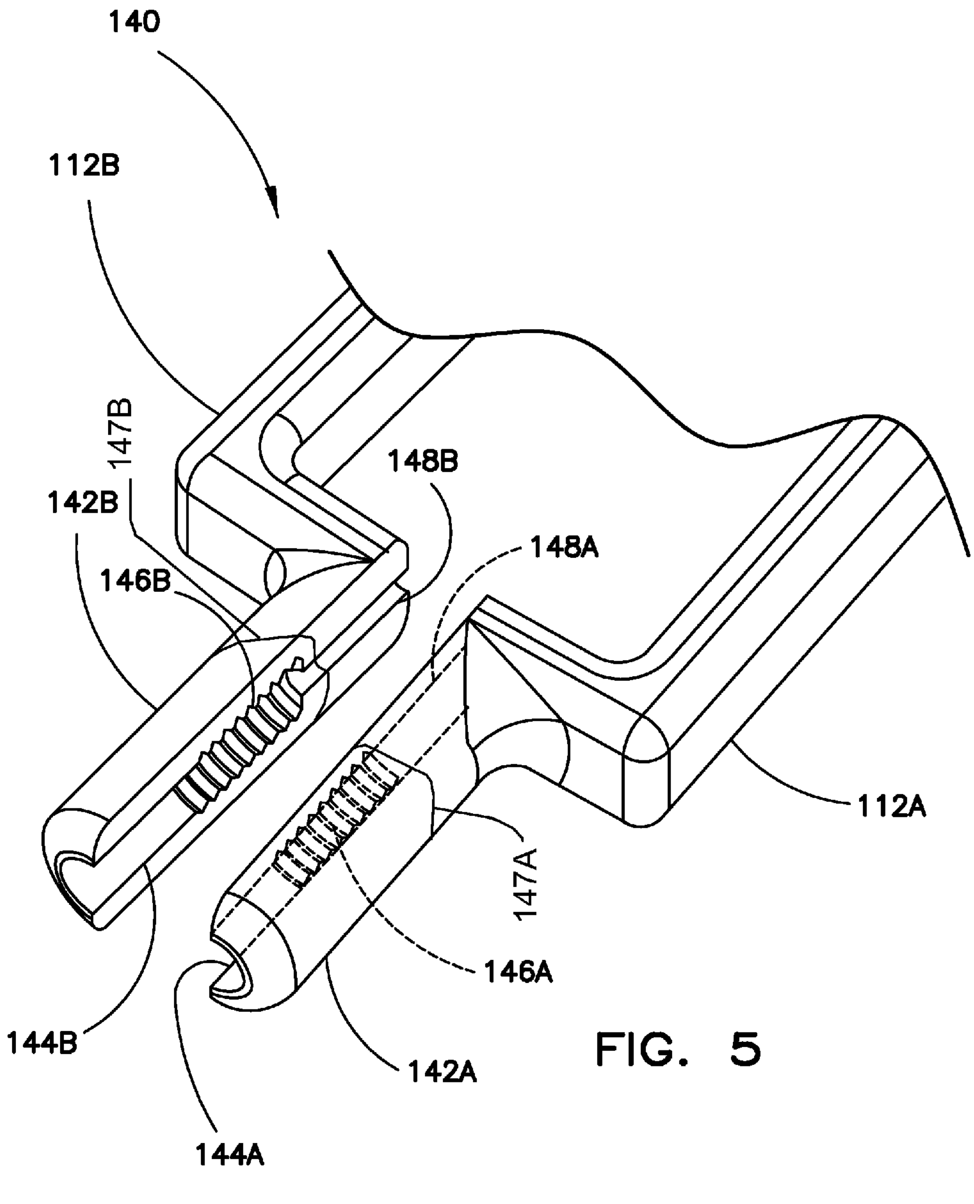
140
112B
147B
148B
142B
148A
146B
112A
147A
146A
144B
142A
144A

FIG. 5

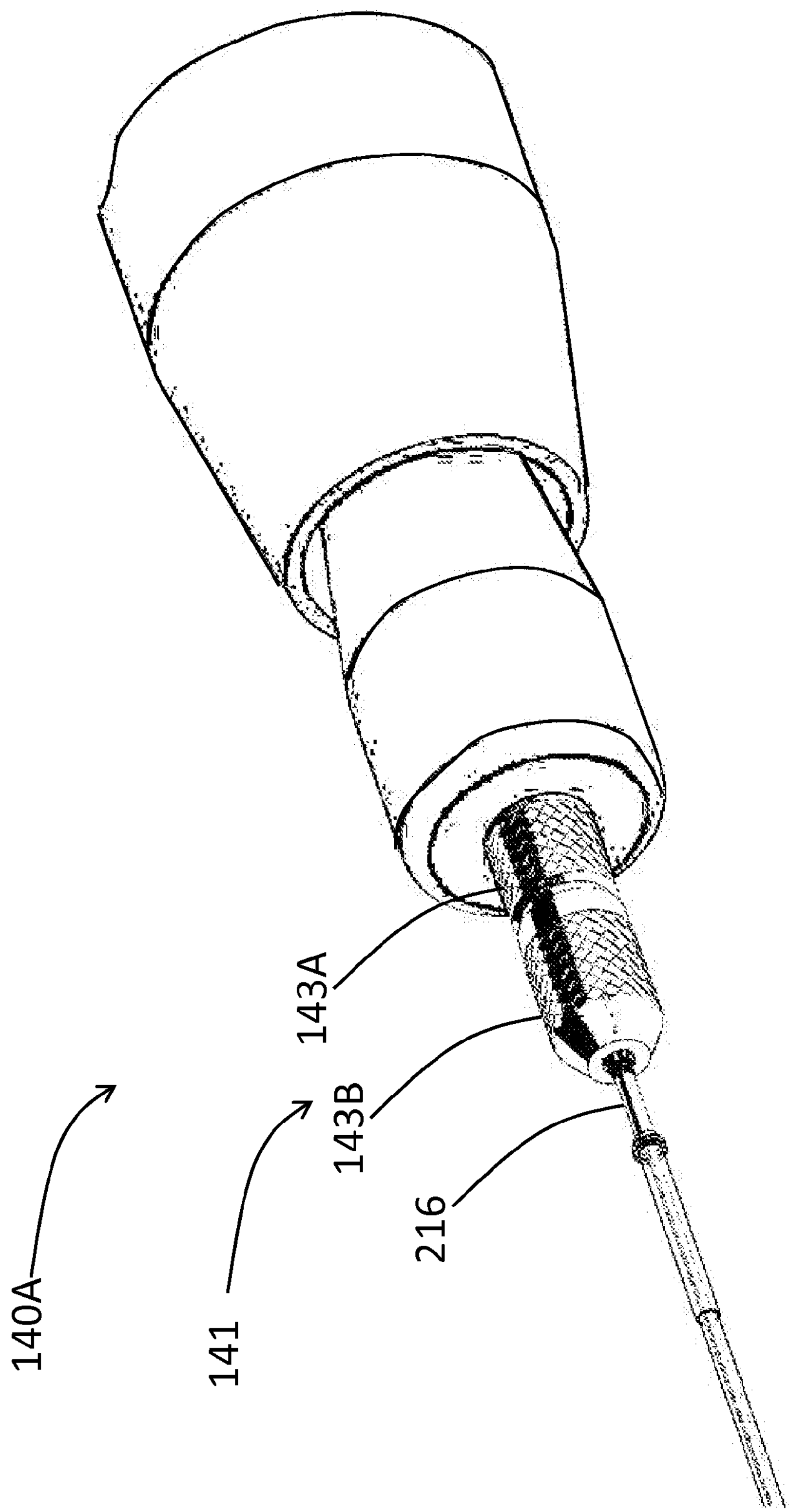

FIG. 5A

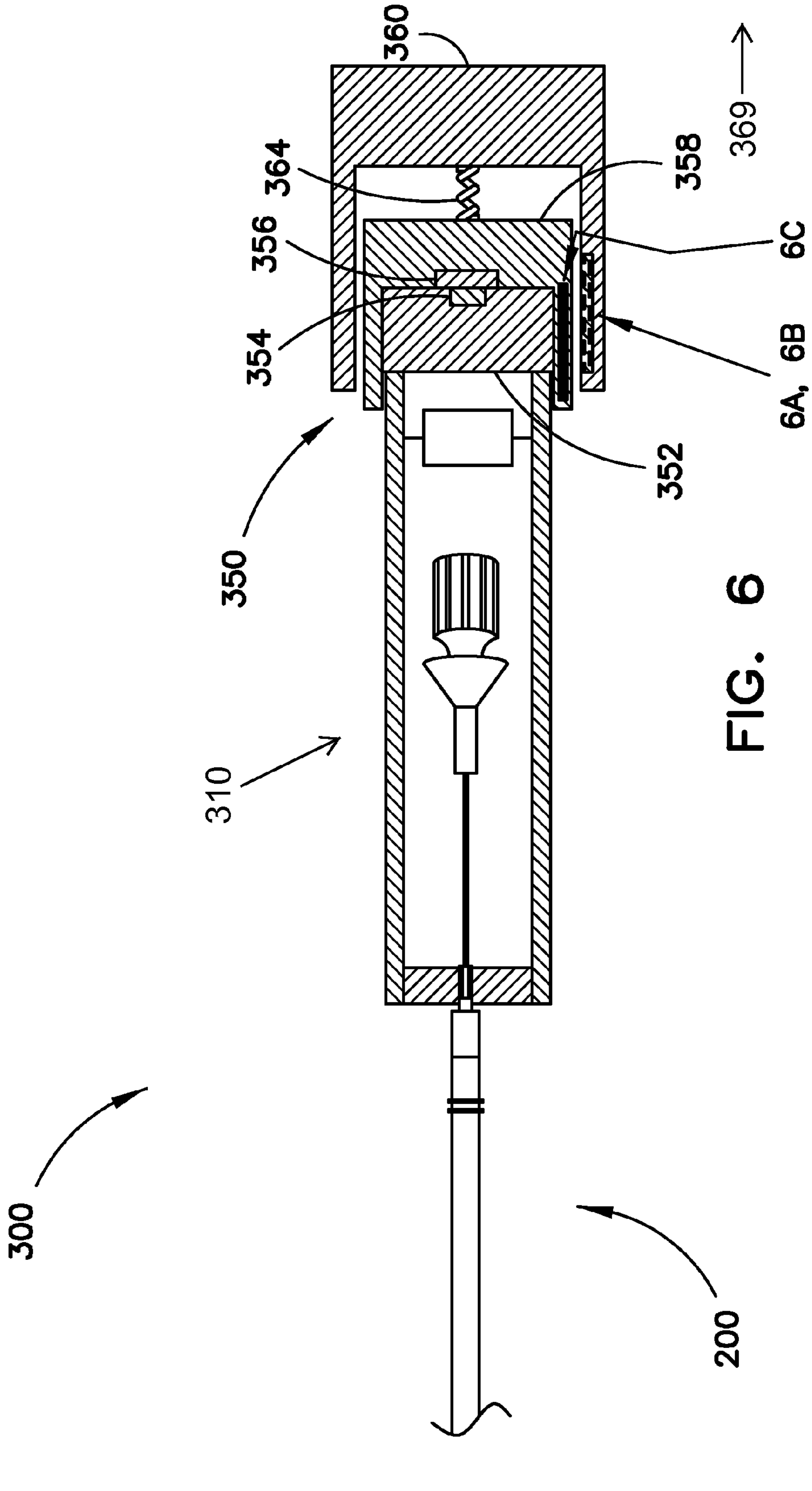

FIG. 6

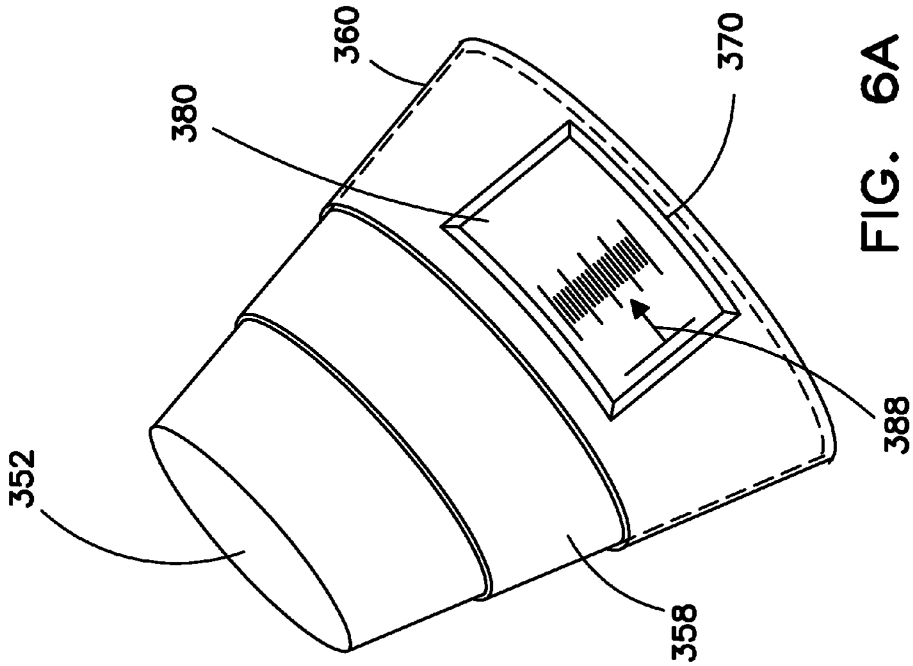

FIG. 6A

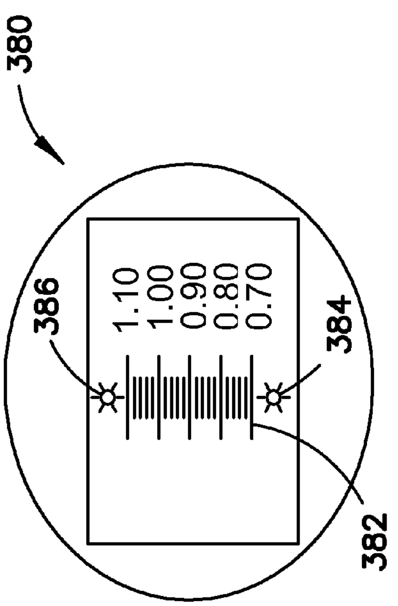

FIG. 6B

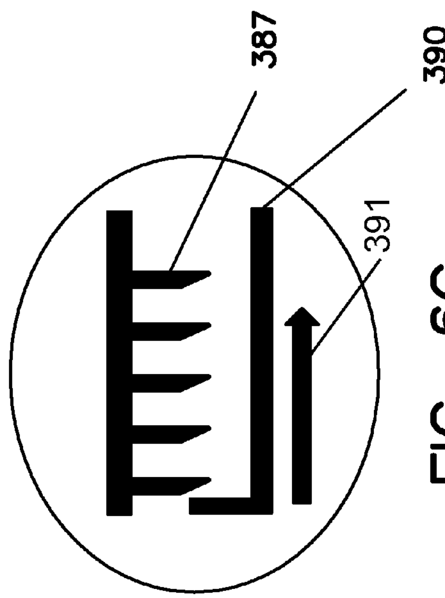

FIG. 6C

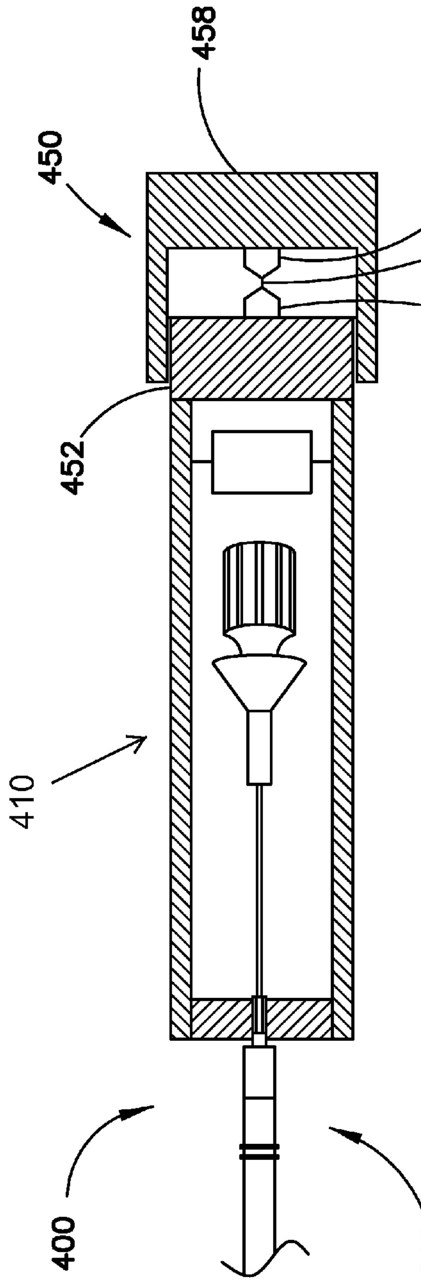
450
458
460
464
462
452
410
400
200

FIG. 7

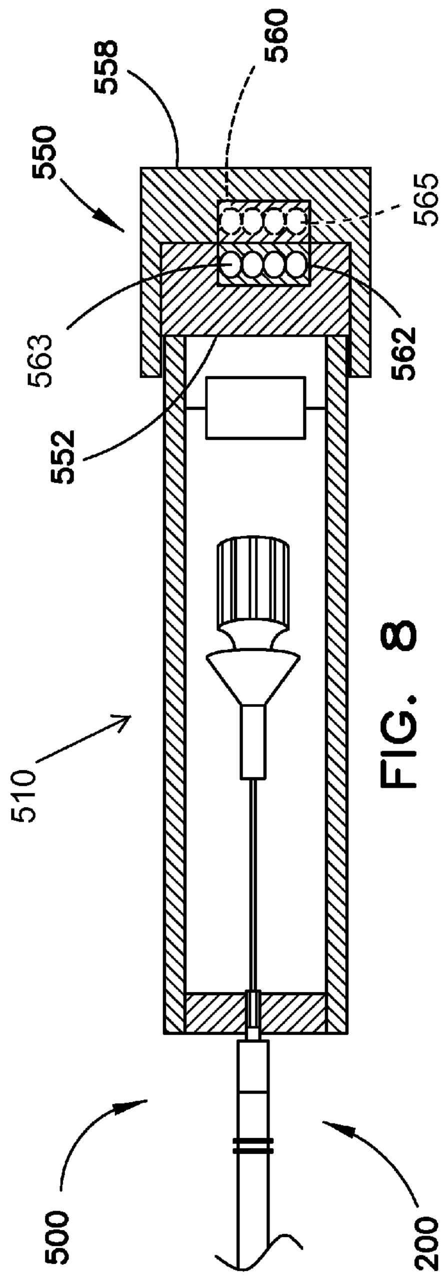
550
558
560
565
563
562
552
510
500
200

FIG. 8

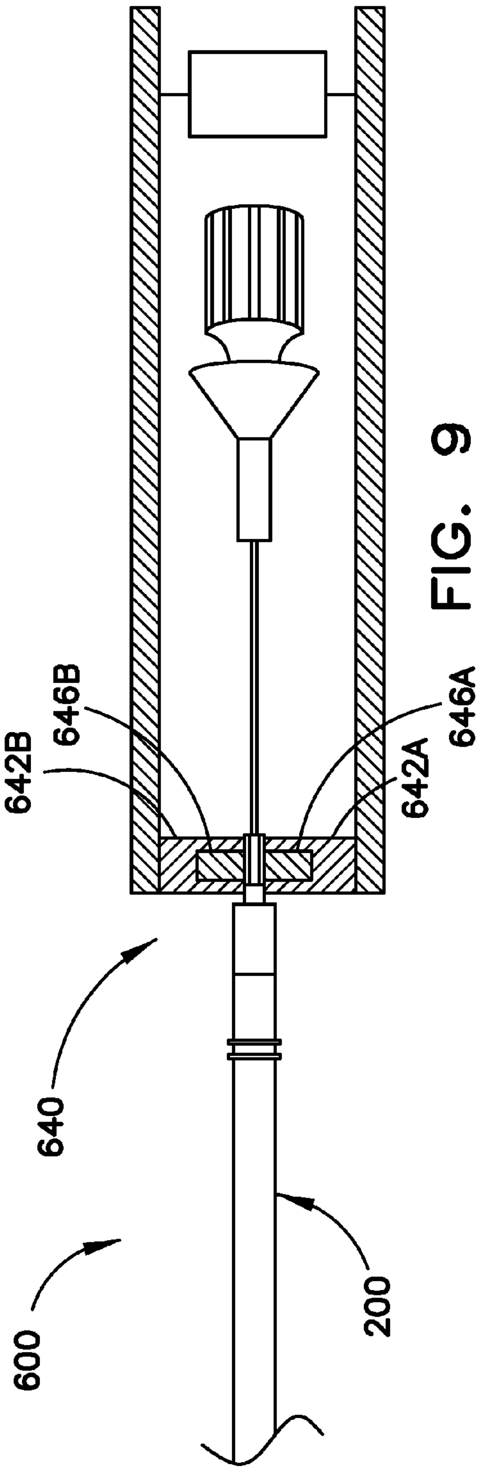

FIG. 9

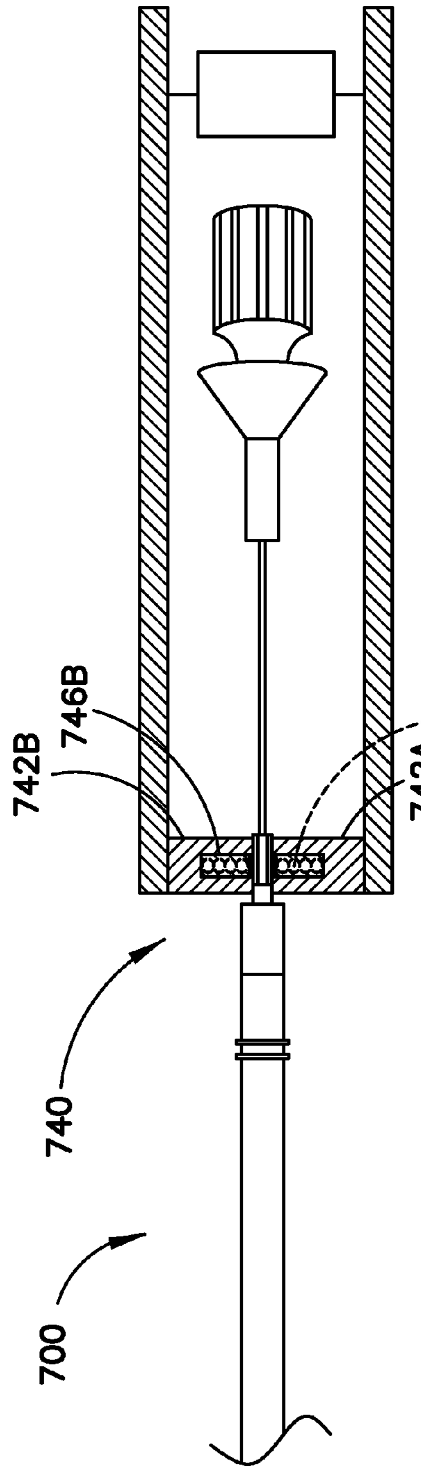

FIG. 10

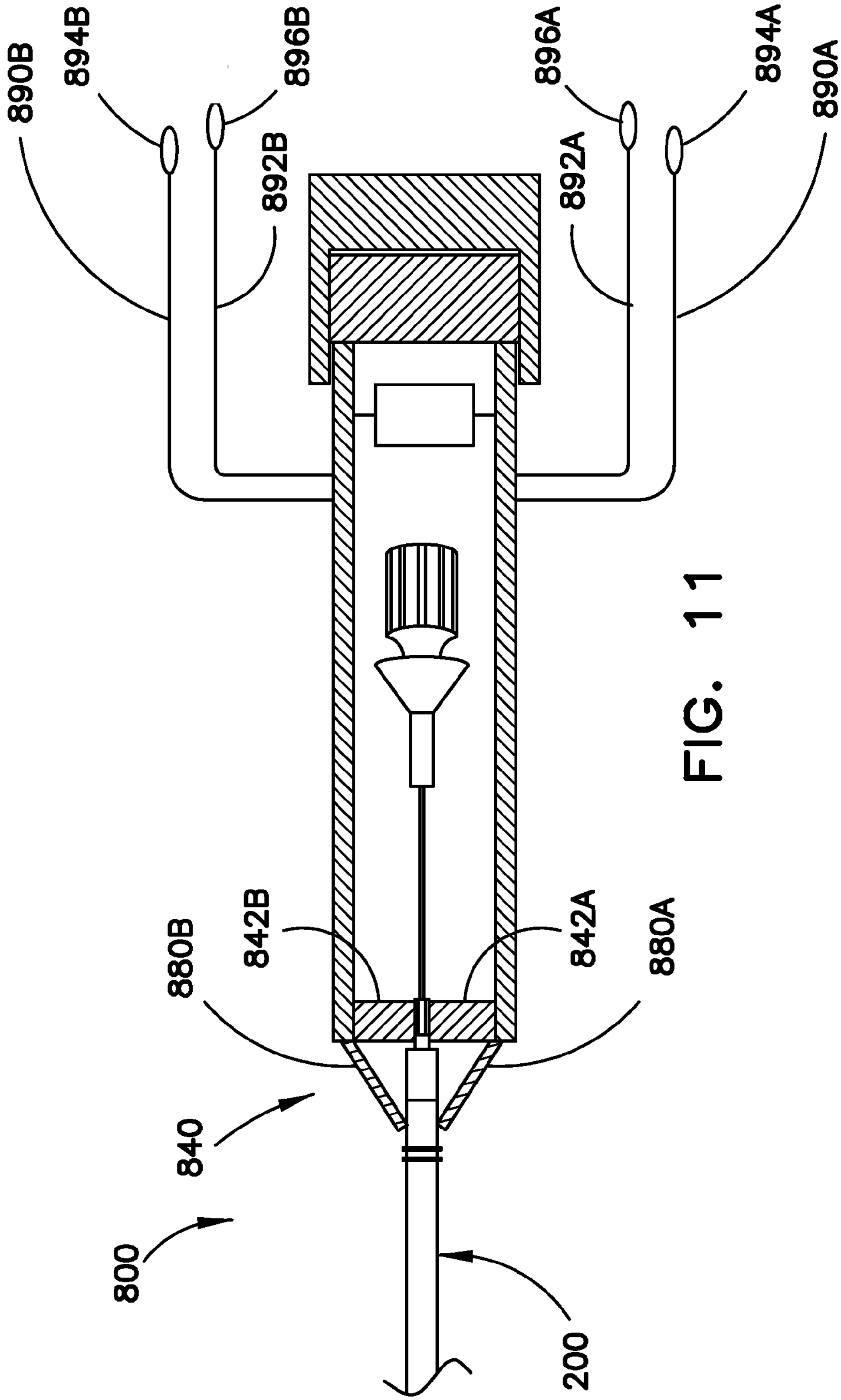
890B
894B
896B
892B
896A
894A
890A
892A
842B
842A
880B
880A
840
800
200

FIG. 11

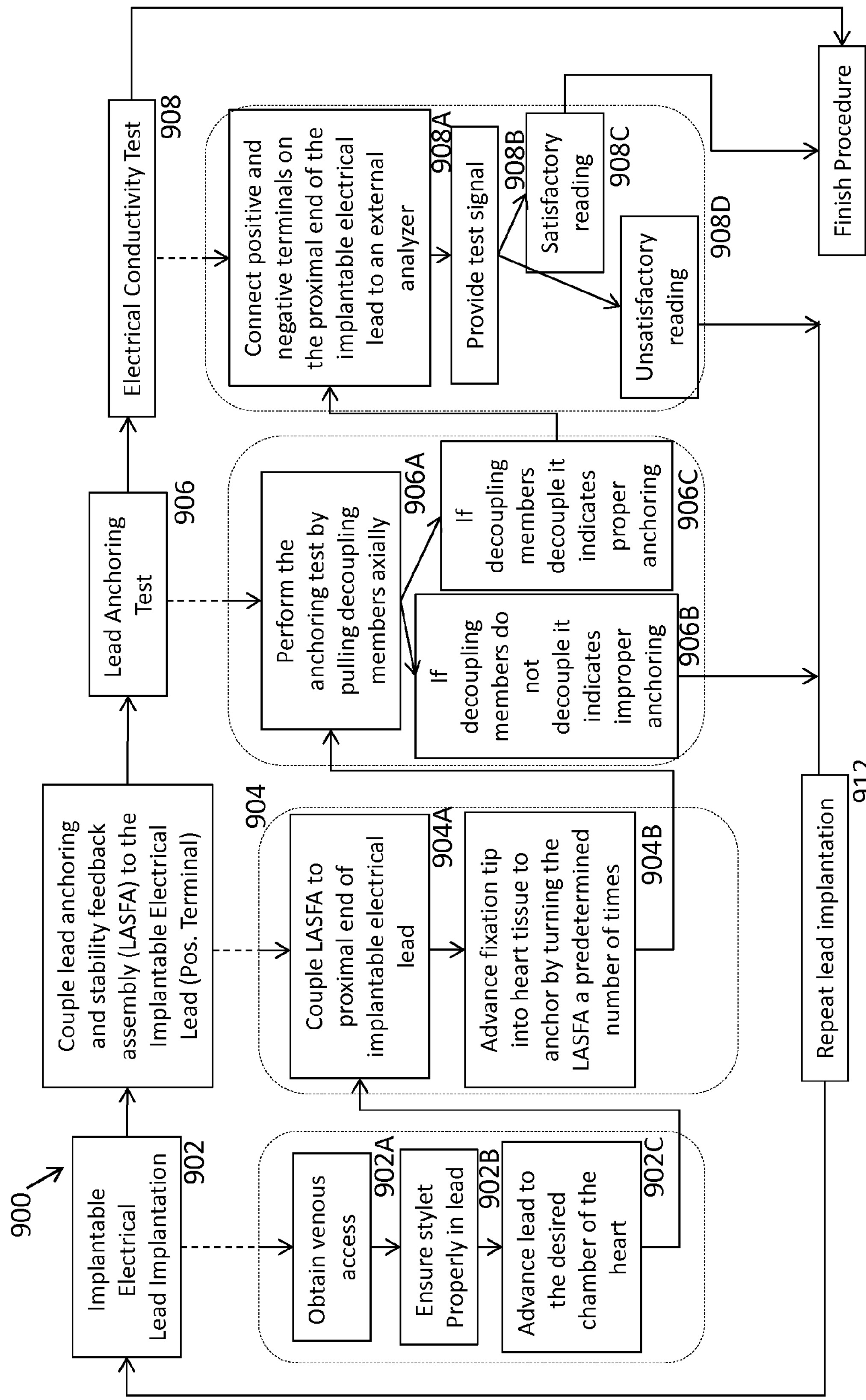
900
Implantable Electrical Lead Implantation
902
Obtain venous access
902A
Ensure stylet Properly in lead
902B
Advance lead to the desired chamber of the heart
902C
Couple lead anchoring and stability feedback assembly (LASFA) to the Implantable Electrical Lead (Pos. Terminal)
904
Couple LASFA to proximal end of implantable electrical lead
904A
Advance fixation tip into heart tissue to anchor by turning the LASFA a predetermined number of times
904B
Lead Anchoring Test
906
Perform the anchoring test by pulling decoupling members axially
906A
If decoupling members do not decouple it indicates improper anchoring
906B
If decoupling members decouple it indicates proper anchoring
906C
Electrical Conductivity Test
908
Connect positive and negative terminals on the proximal end of the implantable electrical lead to an external analyzer
908A
Provide test signal
908B
Satisfactory reading
908C
Unsatisfactory reading
908D
Finish Procedure
910
Repeat lead implantation
912

FIG. 12

FEEDBACK SYSTEM AND METHOD FOR ASSESSING FIXATION AND STABILITY OF IMPLANTABLE LEADS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present U.S. patent application is related to and claims the priority benefit of U.S. Provisional Patent Application Ser. No. 61/734,563, filed Dec. 7, 2012, the contents of which is hereby incorporated by reference in its entirety into the present disclosure.

STATEMENT REGARDING GOVERNMENT FUNDING

This invention was made with government support under EB013029 awarded by the National Institutes of Health. The government has certain rights in the invention.

TECHNICAL FIELD

This disclosure relates to devices requiring implantable lead anchoring, and in particular to generating fixation and stability feedback information for the implanted lead.

BACKGROUND

Implantable leads have numerous applications and are commonly used in medical devices to record electrical activity and/or stimulate a target site. An example of a widespread use of implantable leads in medical devices is in pacemaker or implantable cardioverter-defibrillator (ICD) implantations. Devices such as pacemakers are implanted into the heart as part of artificial cardiac pacing or cardiac resynchronization therapy, which involves generating electrical impulses that are carried by the pacing lead to the heart tissue fibers, signaling them to contract and relax properly. The implantable lead has a distal end and a proximal end. The distal end makes contact with the heart tissue and the proximal end is configured to make contact with the pacing pulse generator. Furthermore, at each end there are two electrical terminals. In particular, at the distal end there is a negative and a positive terminal, and at the proximal end there is a corresponding negative and a positive terminal. Therefore, the negative terminal of the distal end is electrically coupled to the negative terminal of the proximal end, and the positive terminal of the distal end is electrically coupled to the positive terminal of the proximal end. The positive terminals and negative terminals are electrically isolated from each other.

Pacemaker and implantable cardiac device (ICD) leads are anchored to tissue using a fixation mechanism. The lead is typically introduced into the venous system under the patient's collarbone, and its distal end is advanced toward the patient's heart by guiding the lead until the distal end has reached the desired heart wall location in the atrial or ventricular chamber.

There are two common types of fixation mechanisms used to anchor an ICD lead to tissue: active and passive fixation. The passive fixation mechanisms have a plurality of flexible tines that protrude from the distal end of the implantable lead. When the distal end of the lead is pushed into the cardiac tissue the tines latch onto the tissue in order to secure the fixation tip in place. Active fixation mechanisms, by contrast, have a corkscrew-like apparatus at the distal end of the lead which is retracted while the lead is guided to the heart. Once the clinician has determined the desired fixation position (using various imaging technologies and tactile feedback), current practice of anchoring the distal end of the lead to the heart wall involves using a disposable tool to turn a fixation pin at the proximal end of the lead. The clinician turns the pin a predetermined number of times causing advancement of the corkscrew-like apparatus at the distal end into the tissue. Using this method, the clinician attempts to ensure that the lead has an adequate hold on the tissue. The success of anchoring is determined based on several factors including tactile feedback, electrical measurements, and the overall experience of the clinician.

The tactile feedback method typically involves gently tugging on the proximal end of the lead, prior to taking electrical measurements. If the distal end remains secured, the clinician may be satisfied with anchoring. The tactile feedback method relies on subjective standards. The electrical measurement includes connecting the negative and positive terminals of the proximal end to an electrical measurement device. Here, various signals are communicated through the proximal end terminals to the distal end terminals enabling the measurement of conductivity, impedance, electrocardiogram (ECG) amplitudes, pacing thresholds, maximum output and slew rate at the distal end. While the electrical measurement method provides some objective data, it may be difficult to correlate the electrical data obtained from the measurement to how well the lead is anchored in the tissue. The clinician preference may include viewing the lead anchoring in the tissue via various imaging technologies, the tactile feedback method, and/or the electrical measurement method.

The above-described pacemaker implantation methods, however, can result in complications. Common complications include lead malposition (i.e., situations where the lead is not properly placed, potentially resulting in undesired lead penetration into the tissue) or migration (i.e., the lead has moved from the desired location). Lead migration can result in undesirable complications indicated by changes in conductivity which can increase pacing thresholds required to stimulate the heart, decreased sensing ability of the pacemaker, and can thus lead to decreased device performance or even life-threatening consequences. Perforation of the heart wall caused by lead penetration to the tissue can result in various complications, including pericardial effusion.

Aside from pacemakers and ICDs, there are a number of other applications of implantable leads. These applications include: spinal cord stimulators; spinal fusion stimulators; bone growth stimulators; implantable electrocardiogram systems; neuromodulation systems (for example, to be used in cochlear implants, vagus nerve stimulators, deep-brain stimulators, sacral nerve stimulation, implantable electromyography recording devices, migraine treatment, spinal cord injuries, and pain management); and subarachnoid stimulators. All these applications may include a lead anchoring in a respective tissue as described above. Similarly, these other applications may suffer from the same or similar complications as described above.

In view of the foregoing, there is an unmet need for a reliable and efficient system which can provide effective feedback for ensuring proper anchoring of an implantable lead into tissue.

SUMMARY

A lead fixation and stability feedback assembly for testing stability and anchoring of a fixation tip of a distal end of an implantable lead to a tissue is disclosed. The assembly includes a first member including a first coupling arrangement configured to couple to a proximal end of an implantable

lead, wherein the proximal end of the implantable lead is coupled to a distal end of the implantable lead configured to be anchored to a tissue, and a second member including a second coupling arrangement configured to couple the first member to the second member, the second coupling arrangement configured to decouple the second member from the first member when a predetermined force is applied to pull the second member away from the first member to thereby test the anchoring of the distal end of the implantable lead to the tissue.

A method of testing anchoring and stability of an implantable lead to a tissue is also disclosed. The method includes anchoring a fixation tip of a distal end of the implantable lead into a tissue, providing a predetermined force to a second member coupled to a first member, the first member coupled to the proximal end of the implantable lead, and verifying the second member decouples from the first member when the predetermined force is applied.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1**A illustrates a general implantable lead having a proximal end for sending and receiving electrical signals and a distal end for communicating the electrical signals to a tissue.

FIG. **1**B illustrates a lead fixation and stability feedback assembly with a lead clamp assembly in an open position about the proximal end of the implantable lead presented in FIG. **1**A.

FIG. **2** illustrates a side view of the lead fixation and stability feedback assembly with a magnetic coupling arrangement.

FIG. **3** illustrates a perspective view of the lead fixation and stability feedback assembly, with the lead clamp assembly in a closed position.

FIG. **4** illustrates a side view of a proximal end of the lead fixation and stability feedback assembly depicting decoupling of a proximal feedback member of the lead fixation and stability feedback assembly.

FIG. **5** illustrates a perspective view of the lead clamp assembly in the open position.

FIG. **5**A illustrates a side view of a lead fixation and stability feedback assembly with an alternate lead clamp assembly having a pin-vise lead attachment mechanism depicted in a closed position.

FIG. **6** illustrates a schematic of an embodiment of the lead fixation and stability feedback assembly that includes a biased coupling arrangement.

FIG. **6**A illustrates a perspective view of a force scale arrangement as part of the alternate embodiment shown in FIG. **6** of the lead fixation and stability feedback assembly.

FIG. **6**B illustrates a front view of the force scale shown in FIG. **6**A.

FIG. **6**C illustrates a schematic of an alternate embodiment of an alternative lead fixation and stability feedback mechanism including a tooth and a plurality of locking gears.

FIG. **7** illustrates a schematic of an alternate embodiment of the lead fixation and stability feedback assembly with a mechanical decoupling mechanism.

FIG. **8** illustrates a schematic of an alternate embodiment of the lead fixation and stability feedback assembly with an electromagnetic coupling mechanism.

FIG. **9** illustrates a schematic of an alternate embodiment of the lead fixation and stability feedback assembly with a lead clamp assembly that includes one or more magnets.

FIG. **10** illustrates a schematic of an alternate embodiment of the lead fixation and stability feedback assembly with a lead clamp assembly that includes one or more electromagnets.

FIG. **11** illustrates a schematic of an alternate embodiment of the lead fixation and stability feedback assembly which includes electrical terminals.

FIG. **12** illustrates a flow chart describing a method of using the lead fixation and stability feedback assembly.

DETAILED DESCRIPTION

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present disclosure provides methods and systems to address lead anchoring and stability complications described above by providing informative feedback to a clinician when implanting a lead in a tissue. It should be appreciated that tissue in the present disclosure applies to any biological, physiological, or synthetic material that is intended to represent human or animal tissue.

Implantable Lead

Referring to FIG. **1**A, an implantable lead **200** is depicted. The implantable lead **200** comprises a distal end **201** coupled to a proximal end **203**. The distal end **201** is configured to make contact with a tissue (not shown), with a fixation tip **214** configured to provide anchoring and coupling (mechanical and electrical) with the tissue (not shown). The implantable lead **200** further comprises a negative terminal coupling lead **204** disposed in between and configured to couple negative terminals **208**A and **208**B, a positive terminal coupling lead **210** disposed in between and configured to couple a positive terminal **216** and a fixation tip **214**.

The implantable lead **200** further comprises electrically insulating members **206** and **212**. The electrically insulating member **206** is disposed between and is configured to electrically isolate the negative terminal **208**A from the fixation tip **214**. The electrically insulating member **212** is disposed between and is configured to electrically isolate the negative terminal **208**B from the positive terminal **216**.

The positive terminal **216** while positioned next to the negative terminal **208**B is configured to rotate with respect to the negative terminal **208**B. Similarly, the fixation tip **214** while positioned next to the negative terminal **208**A is configured to rotate with respect to the negative terminal **208**A. By the coupling of the positive terminal **216** and the fixation tip **214** (via the positive terminal coupling lead **210**), rotating the positive terminal **216** results in rotation of the fixation tip **214** with the negative terminals **208**A and **208**B substantially stationary. As will become apparent below, a lead fixation and stability feedback assembly **110** (see FIG. **1**B) is configured to grip the positive terminal **216** and rotate it causing the fixation tip **214** to be advanced into a tissue (not shown).

The implantable lead **200** further comprises of a polymeric insulation sleeve **202** that extended from the distal side of the negative terminal **208**B to the proximal side of the negative terminal **208**A. The polymeric insulation sleeve **202** is configured to isolate the negative terminal coupling lead **204** and the remainder of the implantable lead **200** from its outside environment, both electrically and environmentally.

While note shown, the positive terminal coupling lead **210** and negative terminal coupling lead **204** are also electrically isolated from one another by an electrically isolating material.

The implantable lead **200** further comprises a stylet assembly **220**. The stylet assembly **220** comprises a stylet wire **221**, a stylet guide **222**, and a stylet tip **224**. The stylet guide **222** includes a through-hole configured to allow the stylet wire **221** to feed through. While the stylet tip **224** is affixed to the stylet wire **221**, the stylet guide **222** is configured to slide over the stylet wire **221**. The stylet assembly **220** is positioned inside the implantable lead **200** prior to the implantable lead **200** being positioned in the patient. The purpose of the stylet assembly **220** is to make it easier to guide the implantable lead **200** into the patient; and the purpose of the stylet guide **222** is to make it easier to feed the stylet wire **221** into the implantable lead **200**. The stylet assembly **220** is configured to provide a degree of rigidity to the implantable lead **200**, which without the stylet assembly is considerably flexible at the distal end **201**.

As described above, electrical measurements to test lead functionality at the distal end **201** of the implantable lead **200**, specifically between the fixation tip **214** and the negative terminal **208**A, are taken at the proximal end, specifically between the positive terminal **216** and the negative terminal **208**B.

Lead Fixation and Stability Feedback Assembly

Referring to FIG. **1**B, a lead fixation and stability feedback system **100** is depicted. The lead fixation and stability feedback system **100** includes the lead fixation and stability feedback assembly **110** and the implantable lead **200**. The lead fixation and stability feedback assembly **110** is depicted in an open position about the implantable lead **200**. The open and closed positions of the lead fixation and stability feedback assembly **110** can be achieved by pressing on a second handle **120**B against a first handle **120**A (depicted in FIG. **2**), or releasing the second handle **120**B causing opening and closing of a lead clamp assembly **140** (See FIG. **2**). Arrows **115** depict the relative movement of the second handle **120**B into the open position. Also depicted in FIG. **1**B is a decoupling assembly **150** further described below (See FIGS. **2**, **3**, and **4**). The decoupling assembly **150** is depicted in a decoupled state in FIGS. **1**B and **2**, while it is depicted in a coupled state in FIG. **3**.

Referring to FIGS. **2** and **3**, a side view and a perspective view of the lead fixation and stability feedback assembly **110** are depicted in the open and closed positions, respectively. The lead fixation and stability feedback assembly **110** comprises a lead clamp assembly **140**, a distal first arm **112**A coupled to a proximal first arm **114**A, a distal second arm **112**B coupled to a proximal second arm **114**B, a biasing member **118**, a first handle **120**A, and a second handle **120**B. A fulcrum **113** couples the distal first arm **112**A, the proximal first arm **114**A, the distal second arm **112**B, and the proximal second arm **114**B together allowing relative movements of a combination of the distal first arm **112**A and the proximal first arm **114**A as one solid member with respect to a combination of the distal second arm **112**B and the proximal second arm **114**B as another solid member. The biasing member **118**, e.g., a spring, is coupled to a first biasing member connector **116**A and a second biasing member connector **116**B. The first biasing member connector **116**A is coupled to the proximal first arm **114**A and the second biasing member connector **116**B is coupled to the proximal second arm **114**B. The first handle **120**A is coupled to the proximal first arm **114**A and the second handle **120**B is coupled to the proximal second arm **114**B. In FIG. **2**, the double arrows **115** again depict the movement of the second handle **120**B to achieve the open position. It should be noted that when in the closed position, the spacing denoted by the double arrows **115** is enlarged (See FIG. **4**).

The lead fixation and stability feedback assembly **110** further includes a decoupling assembly **150** disposed on the proximal end of the lead fixation and stability feedback assembly **110** opposing the distal end where the lead clamp assembly is positioned.

Referring to FIG. **4**, a side view of the decoupling assembly **150** is depicted with respect to the proximal end of the lead fixation and stability feedback assembly **110**. The decoupling assembly **150** comprises a proximal feedback member **158** coupled to a proximal decoupling device **156** and a distal feedback member **152** coupled to a distal decoupling device **154**. The proximal decoupling device **156** is coupled to the distal decoupling device **154**. In the embodiment depicted in FIG. **4**, the proximal decoupling device **156** and the distal decoupling device **154** are both magnets. As illustrated in FIG. **4**, the proximal decoupling device **156** is configured to decouple from the distal decoupling device **154** upon application of a predetermined amount of decoupling force applied axially. The predetermined amount of decoupling force is determined according to the specific application of the implantable lead **200**. The interface should be designed such that when the decoupling force is applied to the proximal decoupling device **156** from 0 N to the predetermined force, the proximal decoupling device **156** maintains contact with the distal decoupling device **154** until the predetermined force is reached at which point the proximal decoupling device **156** separates from the distal decoupling device **154**. The predetermined force according to the embodiment depicted in FIG. **4** for a pacemaker application using an active fixation apparatus is about 0.9 N+/−0.1 N. Attaining the predetermined force level indicates adequate anchoring of the implantable lead **200** to the tissue (not shown). Therefore, exerting a decoupling force up to 0.9 N+/−0.1 N should not cause a premature separation between the proximal decoupling device **156** and the distal decoupling device **154**. It should be appreciated, however, that the predetermined force of 0.9 N+/−0.1 N is based on a cardiac application and further based on the type of fixation tip **214** (See FIG. **1**A). It should be noted that the predetermined force is based on one application. Furthermore, it should be appreciated that insertion of the fixation tip in a non-cardiac muscle tissue, e.g., into bone, cartridge, or brain tissue, will require different predetermined force levels. By choosing different pairs of the proximal decoupling device **156** and the distal decoupling device **154**, different predetermined force levels can be realized.

It should further be noted that when the lead fixation and stability feedback assembly **110** is in the closed position and the proximal feedback member **158** is placed adjacent and coupled to the distal feedback member **152** (as depicted in FIG. **3**), the proximal feedback member **158** prevents relative movement of the second handle **120**B to avoid inadvertent placing the lead fixation and stability feedback assembly **110** in the open position. Therefore, in order to move the second handle **120**B, the proximal feedback member **158** must first be removed.

Referring to FIG. **5**, a perspective view of one embodiment of the lead clamp assembly **140** is depicted in an open position. The lead clamp assembly **140** includes a first jaw **142**A and a second jaw **142**B. The first jaw **142**A is coupled to the distal first arm **112**A and the second jaw **142**B is coupled to the distal second arm **112**B. The first jaw **142**A and the second jaw **142**B are configured to be disposed on the proximal end **203** of the implantable lead **200** (See FIG. **1**A). The first jaw **142**A in FIG. **5** includes terminal jaw sections **148**A and **144**A, configured to be disposed on and electrically coupled to the positive terminal **216** and the negative terminal **208**B, respectively, of the implantable lead **200** (see FIG. **1**A). The first jaw **142**A of FIG. **5** further includes a grooved jaw section **146**A, approximately centered with respect to the terminal jaw sections **148**A and **144**A, and configured to be disposed and mechanically coupled to the electrically insulating member **212**. Furthermore, the grooved jaw section **146**A is configured to electrically isolate terminal jaw sections **148**A and **144**A. Similarly, the second jaw **142**B includes terminal jaw sections **148**B and **144**B, configured to be disposed on and electrically coupled to the positive terminal **216** and the negative terminal **208**B, respectively, of the implantable lead **200** (see FIG. **1**A). The second jaw **142**B further includes a grooved jaw section **146**B, approximately centered with respect to the terminal jaw sections **148**B and **144**B, and configured to be disposed and mechanically coupled to the electrically insulating member **212**. Furthermore, the grooved jaw section **146**B is configured to electrically isolate terminal jaw sections **148**B and **144**B.

In order for the lead clamp assembly **140** to be able to both rotate the positive terminal **216** and yet make electrical measurements by coupling to the negative terminal **208**B, not only do the jaw sections **148**A and **148**B have to be electrically isolated from the jaw sections **144**A and **144**B, respectively, the jaw sections **148**A and **148**B have to be mechanically isolated from the remainder of the first and second jaws **142**A and **142**B, respectively. In other words, the jaw sections **148**A and **148**B and the remainder of the lead clamp assembly **140** to the right of the jaw sections **148**A and **148**B (as depicted in FIG. **5**) are configured to rotate while the grooved jaw sections **146**A and **146**B and the jaw sections **144**A and **144**B remain stationary. Accordingly, break lines **147**A and **147**B are depicted in FIG. **5** to illustrate a break between the respective sections of the first and second jaws **142**A and **142**B.

While not shown, in an alternative embodiment, the lead clamp assembly **140** can be provided without the jaw sections **144**A and **144**B and the grooved jaw sections **146**A and **146**B. In this embodiment, an example of which is depicted in the schematic of FIG. **6**, the jaw sections **148**A and **148**B are the only extruding members of the first and second jaws **142**A and **142**B.

While not shown in FIG. **5**, jaw sections **144**A, **144**B, **148**A, and **148**B can be coupled to four lead wires (See FIG. **11**). The lead wires can be reduced down to two by internally connecting each set of lead wires, as further described below.

There are two positions (open and closed) shown in FIGS. **2** and **3**. As described above, when a force is applied to the first and second handles **120**A and **120**B, in order to move the second handle **120**B which is movable towards the first handle **120**A which is stationary, the lead fixation and stability feedback assembly **110** can be moved from the closed position (see FIG. **3**) to the open position (See FIG. **2**). As described below in the operation portion of the present disclosure, when in the open position, the lead clamp assembly **140** can be placed over the positive terminal **216**, the electrically insulating member **212**, and the negative terminal **208**B (according to the embodiment of the lead clamp assembly **140** shown in FIG. **5**), or only over the positive terminal **216** (according to the embodiment of the lead clamp assembly depicted in the schematic of FIG. **6**); and once properly positioned, the force holding the lead clamp assembly **140** in the open position removed to allow the lead clamp assembly **140** to grip the positive terminal **216**, the insulating member **212** and the negative terminal **208**B (or just the positive terminal **216** depending on which lead clamp assembly **140** is used in the embodiments depicted in FIGS. **5** and **6**). The resulting position (not shown) is henceforth referred to as a pseudo-closed position. In the pseudo-closed position, the first and second jaws **142**A and **142**B are securely gripping the positive terminal **216**, the insulating member **212**, and the negative terminal **208**B. As described above, the grooved jaw sections **146**A and **146**B are configured to mechanically grip the electrically insulating member **212** in order to prevent relative movement between the lead clamp assembly **140** and the positive terminal **216** when the decoupling force is being applied to the proximal decoupling device **156** and when the lead clamp assembly **140** is in the pseudo-closed position.

Referring to FIG. **5**A, a perspective view of an alternative embodiment of a lead clamp assembly **140**A is depicted. The lead clamp assembly **140**A includes a pin-vise lead attachment mechanism **141** which includes tightening members **143**A and **143**B (as is known to a person having ordinary skill in the art). The tightening member **143**B is configured to rotate with respect to tightening member **143**A, thereby allowing the pin-vise lead attachment mechanism **141** to tightly grip the positive terminal **216**. In this embodiment, the stylet assembly **220** has been removed to avoid interference with the lead clamp assembly **140**A.

Referring to FIG. **6**, a schematic of another embodiment of a lead fixation and stability feedback system **300** is depicted. The lead fixation and stability feedback system **300** includes the implantable electric lead **200** and a lead fixation and stability feedback assembly **310**. The lead fixation and stability feedback assembly **310** is similar to the lead fixation and stability feedback assembly **110**, with the exception that its corresponding lead fixation and stability feedback mechanism **350**, in addition to its corresponding distal feedback member **352**, distal decoupling device **354**, proximal feedback member **358**, and proximal decoupling device **356**, includes a force feedback member **360** and a biasing member **364**. As with the lead fixation and stability feedback mechanism **150** (see FIG. **4**), the distal decoupling device **354** of the lead fixation and stability feedback mechanism **350** is coupled to a distal feedback member **352**. The distal decoupling device **354** is further coupled to the proximal decoupling device **356**. The proximal decoupling device **356** is coupled to the proximal feedback member **358**. A predetermined force is needed to separate the proximal decoupling device **356** from the distal decoupling device **354**.

The proximal feedback member **358** is coupled to the force feedback member **360** by the biasing member **364**. According to spring mechanics principles, when the force feedback member **360** is axially pulled in the direction of arrow **369** from the proximal feedback member **358**, a linearly increasing force is translated on the proximal feedback member **358**. Once the force reaches the predetermined force, the distal decoupling device **354** and the proximal decoupling device **356** decouple. Attaining the predetermined force level indicates adequate anchoring of the implantable lead **200** to the tissue (not shown).

Referring to FIGS. **6**A and **6**B, schematics of an alternative lead fixation and stability feedback mechanism **350** embodiment is depicted. The lead fixation and stability feedback mechanism **350** may include a digital/analog force indicator **380** which may include a force scale **382** (See FIG. **6**B) disposed on the proximal feedback member **358**, displayed in a scale window **370** (See FIG. **6**A) disposed on the force feedback member **360**. The force scale **382** permits the clinician to have additional quantitative feedback through the digital/analog scale indicator **380** with a force indicator **388** to indicate the level of force that is exerted and how much force is required to cause the distal decoupling device **354** to decouple from the proximal decoupling device **356**. In addition, an optional first indicator **384** and an optional second indicator **386**, or a plurality thereof, may be placed on the force scale **382**. This optional first indicator **384** and optional second indicator **386** may be in the form of light emitting diodes configured to indicate when the predetermined force level has been attained. While the necessary control system to activate the optional first indicator **384** and the optional second indicator **386** has not been discussed, such a control system is known to a person having ordinary level of skill in the art.

In yet another embodiment, referring to FIG. **6**C, a schematic of a ratchet-like mechanism in an alternate embodiment of the lead fixation and stability feedback mechanism **350** is depicted. The ratchet-like mechanism may include a plurality of teeth **387** which are attached to the proximal feedback member **358**, with an L-shaped member **390** attached to the force feedback member **360**, configured to slide along the plurality of teeth **387** in proportion to the force level exerted on the biasing member **364**. The ratchet-like mechanism ensures forward movement according to arrow **391**, and accordingly prevents reverse movement unless a release mechanism is activated (known to a person having ordinary skill in the art) to pull the L-shaped member **390** away from the teeth **387** and allowing the biasing member **364** to reverse the force feedback member **360** to move in a direction opposite that of the arrow **391**. With respect to the cardiac pacemaker example discussed above, when the L-shaped member **390** is approximately near the tooth **387** marking 0.9 N, the predetermined force is attained resulting in the decoupling of the proximal and distal decoupling devices **356** and **354**, respectively.

Referring to FIG. **7**, a schematic of another embodiment of a lead fixation and stability feedback system **400** is depicted. The lead fixation and stability feedback system **400** includes the implantable electric lead **200** and a lead fixation and stability feedback assembly **410**. The lead fixation and stability feedback assembly **410** is similar to the lead fixation and stability feedback assembly **110**, with the exception that its corresponding lead fixation and stability feedback mechanism **450**, in addition to its corresponding distal feedback member **452** and proximal feedback member **458**, includes a first decoupling device **462**, a second decoupling device **460**, and a mechanical decoupling member **464**. As with the lead fixation and stability feedback mechanism **150** (see FIG. **4**), the first decoupling device **462** of the lead fixation and stability feedback mechanism **450** is coupled to the distal feedback member **452**. The first decoupling device **462** is further coupled to the second decoupling device **460** via the mechanical decoupling member **464**. The second decoupling device **460** is coupled to the proximal feedback member **458**. A predetermined force is needed to break the mechanical decoupling member **464** allowing separation of the second decoupling device **458** from the first decoupling device **452**.

Referring to FIG. **8**, a schematic of another embodiment of a lead fixation and stability feedback system **500** is depicted. The lead fixation and stability feedback system **500** includes the implantable electric lead **200** and a lead fixation and stability feedback assembly **510**. The lead fixation and stability feedback assembly **510** is similar to the lead fixation and stability feedback assembly **110**, with the exception that its corresponding lead fixation and stability feedback mechanism **550**, in addition to its corresponding distal feedback member **552** and proximal feedback member **558**, includes a first decoupling device **562** and a second optional decoupling device **560**. As with the lead fixation and stability feedback mechanism **150** (see FIG. **4**), the first decoupling device **562** of the lead fixation and stability feedback mechanism **550** is coupled to the distal feedback member **552**. The first decoupling device **562** is further coupled to the second optional decoupling device **560**. The second optional decoupling device **560** is coupled to the proximal feedback member **558**. A predetermined force is needed to separate the proximal feedback member **558** from the distal feedback member **552**. The first decoupling device **562** and the second optional decoupling device **560** are electromagnetic decoupling devices, where wire winding **563** about a core (not shown) generates an electromagnetic attraction with the second optional decoupling device **560**, having a respective winding **565** about a core (not shown), or an attraction with the proximal feedback member **558** in the absence of the second optional decoupling device **560**.

Referring to FIG. **9**, a schematic of another embodiment of a lead fixation and stability feedback system **600** is depicted. The lead fixation and stability feedback system **600** includes the implantable electric lead **200** and an alternate lead clamp assembly **640**. The lead clamp assembly **640** depicted in the pseudo-closed position includes first and second jaws **642**A and **642**B, each including a magnet **646**A and **646**B, respectively. It should be appreciated that in FIG. **9**, the jaws **642**A and **642**B are depicted as only making contact with the positive terminal **216** (See FIG. **1**A). The magnets are intended to provide further gripping force on the positive terminal **216** to ensure no inadvertent relative movement occurs between the positive terminal **216** and the lead fixation and stability feedback system **600**. As discussed in FIG. **8**, one of the magnets **646**A or **646**B can be optional, where in the absence of it, the magnetic attraction is between the other magnet and the opposite jaw.

Referring to FIG. **10**, a schematic of another embodiment of a lead fixation and stability feedback system **700** is depicted. The lead fixation and stability feedback system **700** includes the implantable electric lead **200** and an alternate lead clamp assembly **740**. The lead clamp assembly **740** depicted in the pseudo-closed position includes first and second jaws **742**A and **742**B, each including an electromagnet **746**A and **746**B, respectively. It should be appreciated that in FIG. **10**, the jaws **742**A and **742**B are depicted as only making contact with the positive terminal **216** (See FIG. **1**A). The electromagnets are intended to provide further gripping force on the positive terminal **216** to ensure no inadvertent relative movement occurs between the positive terminal **216** and the lead fixation and stability feedback system **700**.

Referring to FIG. **11**, a schematic of another embodiment of a lead fixation and stability feedback system **800** is depicted. The lead fixation and stability feedback system **800** includes the implantable electric lead **200** and an alternate lead clamp assembly **840**. The lead clamp assembly **840** depicted in the pseudo-closed position includes first and second jaws **842**A and **842**B, respectively. Coupled to each jaw but electrically isolated is a set of spring-loaded tines **880**A and **880**B, configured to make contact with the negative terminal **208**B (See FIG. **1**A). The jaws **842**A and **842**B are electrically coupled to lead wires **892**A and **892**B, respectively, which terminate at terminals **896**A and **896**B, respectively. The spring-loaded tines **880**A and **880**B are electrically coupled to lead wires **890**A and **890**B, respectively, which terminate at terminals **894**A and **894**B, respectively. The four lead wires and associated terminals can be reduced to two lead wires and terminals by internally electrically coupling matching lead wires.

It should be appreciated that while two magnets referenced as decoupling devices are depicted in the figures of the present disclosure, in one embodiment one such decoupling device can be used which may be positioned in either of the feedback members. For example, with regards to FIG. **4**, it should be appreciated that a desired magnetic coupling can be generated with only the distal decoupling device **154** disposed in the distal feedback member **152** without the proximal decoupling device (referenced as **156**) being placed in the distal feedback member **158**.

Operation

Referring to FIG. **12**, a process flow **900** illustrating a method for assuring adequate anchoring and stability of an implantable lead to a tissue is presented. According to FIG. **12**, an implantable lead is first implanted (see blocks **900**, **902**A, **902**B, and **902**C). The presently disclosed lead fixation and stability feedback assembly is then coupled to the implantable lead. Using the lead fixation and stability feedback assembly, the anchoring of the implantable lead to the tissue is tested (See blocks **904**, **904**A, **904**B, and **904**C, **906**, **906**A, **906**B, and **906**C). If decoupling occurs between the decoupling members (e.g., **152** and **158**, See FIG. **4**) of the lead fixation and stability feedback assembly at a force level indicating an adequate anchoring, then the anchoring is deemed appropriate. Verification of the electrical measurements may then be performed after leads (See FIG. **11**) have been connected to an external electrical measurement system (not shown) in order to provide needed signals for the electrical testing (See blocks **908**, **908**A, **908**B, **908**C, and **908**D). Once the electrical conductivity and other electrical parameters (discussed above) are verified, the lead fixation and stability feedback assembly may be removed from the implantable lead, the stylet assembly removed, and the implantable lead may be coupled to the pacemaker (See block **910**). If the lead implantation is deemed to have been unsatisfactory, e.g., premature decoupling of the implantable lead by applying force to the proximal decoupling member or improper electrical test reading, then the lead implantation is repeated (See block **912**).

While the invention has been described with reference to certain embodiments, it will be apparent to those of ordinary skill in the art that other embodiments and implementations are possible that are within the scope of the invention without departing from the spirit and scope of the invention. It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting.

The invention claimed is:

1. A lead fixation and stability feedback assembly for testing stability and anchoring of a fixation tip of a distal end of an implantable lead to a tissue, comprising:

a first member including a first coupling arrangement configured to couple to a proximal end of an implantable lead, wherein the proximal end of the implantable lead is coupled to a distal end of the implantable lead configured to be anchored to a tissue, first coupling arrangement including a lead clamp assembly configured to translate one or more of a mechanical force and a magnetic force to grip the proximal end of the implantable lead; and

a second member including a second coupling arrangement configured to couple the first member to the second member, the second coupling arrangement configured to decouple the second member from the first member when a predetermined force is applied to pull the second member away from the first member to thereby test the anchoring of the distal end of the implantable lead to the tissue.

2. The system of claim **1**, the lead clamp assembly including gripping members configured to translate mechanical forces from a biasing member to grip the proximal end of the implantable lead.

3. The system of claim **1**, the lead clamp assembly including a magnetic arrangement configured to provide magnetic attraction forces to grip the proximal end of the implantable lead.

4. The system of claim **3**, the lead clamp assembly further including gripping members configured to translate mechanical forces from a biasing member to grip the proximal end of the implantable lead.

5. The system of claim **1**, the lead clamp assembly including an electromagnetic arrangement configured to provide magnetic attraction forces to grip the proximal end of the implantable lead.

6. The system of claim **5**, the lead clamp assembly further including gripping members configured to translate mechanical forces from a biasing member to grip the proximal end of the implantable lead.

7. The system of claim **1**, the second coupling arrangement including at least one magnet disposed in one of the first or second members, configured to provide a magnetic attraction force between the first member and the second member, the magnetic attraction force configured to be about the predetermined force.

8. The system of claim **1**, the second coupling arrangement including a first magnet disposed in the first member and a second magnet disposed in the second member, the first and second magnets configured to provide a magnetic attraction force between the first member and the second member, the magnetic attraction force configured to be about the predetermined force.

9. The system of claim **1**, the second coupling arrangement including a mechanical decoupling member configured to break with a force about the predetermined force.

10. The system of claim **1**, the second coupling arrangement including an electromagnetic interface disposed in the first member, the electromagnetic interface configured to provide a magnetic attraction force between the first member and the second member, the magnetic attraction force configured to be about the predetermined force.

11. A lead fixation and stability feedback assembly for testing stability and anchoring of a fixation tip of a distal end of an implantable lead to a tissue, comprising:

a first member including a first coupling arrangement configured to couple to a proximal end of an implantable lead, wherein the proximal end of the implantable lead is coupled to a distal end of the implantable lead configured to be anchored to a tissue;

a second member including a second coupling arrangement configured to couple the first member to the second member, the second coupling arrangement configured to decouple the second member from the first member when a predetermined force is applied to pull the second member away from the first member to thereby test the anchoring of the distal end of the implantable lead to the tissue;

an electrical measurement arrangement including at least one electrical test lead coupled to the fixation tip of the implantable lead and at least one electrical test lead coupled to a return terminal at the distal end of the implantable lead, the two leads configured to provide a signal to measure electrical performance between the fixation tip and the return terminal.

12. A method of testing anchoring and stability of an implantable lead to a tissue, comprising:

anchoring a fixation tip of a distal end of the implantable lead into a tissue;

providing a predetermined force to a second member coupled to a first member, the first member coupled to the proximal end of the implantable lead; and

verifying the second member decouples from the first member prior to reaching the predetermined force.

13. The method of claim **12**, further comprising measuring electrical performance and impedance between the fixation tip and a return terminal positioned at the distal end of the implantable lead.

14. The method of claim **13**, further comprising repeating the anchoring, providing a predetermined force, and the verifying steps if the electrical measurement falls outside of predetermined limits.

15. The method of claim **12**, further comprising repeating the anchoring, providing a predetermined force, and the verifying steps if the verifying step resulted in movement of the second member while the proximal end of implant lead is still coupled to the first member.

16. The method of claim **12**, the second member and the first member are coupled by at least one magnet, configured to provide a magnetic attraction force between the first member and the second member, the magnetic attraction force configured to be about the predetermined force.

17. The method of claim **12**, the second member coupled to the first member by a coupling arrangement including a mechanical decoupling member configured to break with a force about the predetermined force.

18. The method of claim **12**, the second member and the first member are coupled by an electromagnetic interface disposed in the first member, the electromagnetic interface configured to provide a magnetic attraction force between the first member and the second member, the magnetic attraction force configured to be about the predetermined force.

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